Infusomat® Space P
and Accessories

Instructions for Use

It is recommended that all pumps at your ward are equipped with the same software version.

CE 0123

GB Valid for Software 687F

B|BRAUN

CONTENTS

*The availability of the listed features is depending on the configuration of the pump.
**Technical Safety Check

INFUSOMAT® SPACE P OVERVIEW

Arrow up and –down
Scroll through menus, change setting of numbers from 0-9, answer Yes/No questions.
Arrow left and –right
Select data from a scale and switch between digits when numbers are entered. Open a function while pump is running or stopped with the left arrow key.

Press to reset single values to zero and switch back to the previous screen/menu level.

Press to open the pump door.

Yellow LED: Pre-alarm, reminder alarm
Green / Red LED: Infusion occuring / device alarm, operating alarm
Blue LED: Currently connected to SpaceControl

Press to initiate bolus.

Press to turn pump on/off.

OK
Open certain functions and press to confirm values/settings/alarms.

Press to link the pump to SpaceControl and to assign a barcode after scanning.

Start Stop
Press to Start/Stop infusion.

Cover of Battery Compartment
Before changing the battery, always disconnect the pump from the patient and switch off the device.
To remove the battery cover push the button below the battery compartment with a pointed pen and pull the cover away from device. Slide green locking mechanism on back of battery up and take out battery pack for exchange.
A crank in order to open the pump door in case of emergency is attached to the inside of the battery compartment cover (for closer information see 1.4).

Port for drop sensor

Port P3 for future options

Port P2 for power supply, SpaceStation, connection lead (12V), combi lead and further accessory leads (staff call, service)

Pressure sensor

Air sensor

Opening lever

Safety clamp

Signal lamp

Line guide cover

Upstream-sensor
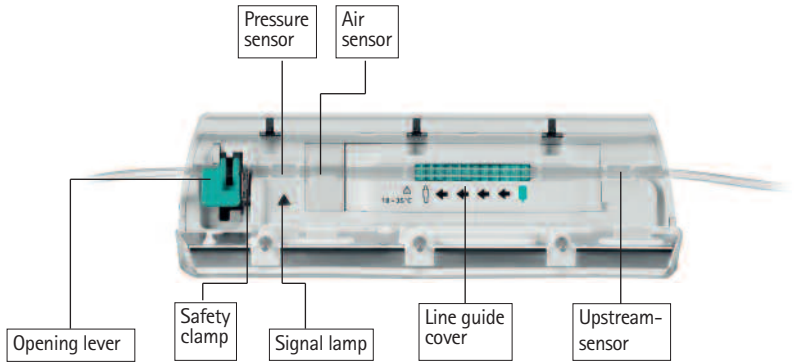
Fixaton of PoleClamp (Universal Clamp)
Line up bar of pump with bar of PoleClamp and slide PoleClamp forward until locking mechanism clicks.
To remove, press release button on frame, push handle down and pull PoleClamp bakkwards.

Transport
A maximum of three pumps (Infusomat® Space P or Perfusor® Space) plus one SpaceControl may be stacked together. Avoid external mechanical influence.

Locking Devices Together
Line up the bar of the lower pump with the bar of the pump above and slide the lower pump backwards until the lock clicks and the green buttons are above each other. To disconnect, push green locking buttons of top pump device and slide bottom pump forward.
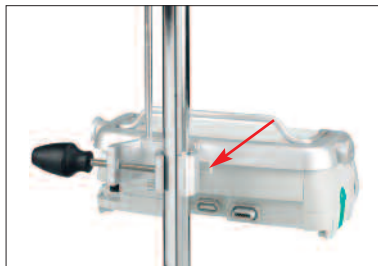
Pole Fixation
Push the opening of the PoleClamp against the vertical pole and lock the screw tightly. Unscrew to release.
For vertical fixation of PoleClamp push lever down and rotate either way until lever clicks into notch. Push lever for rotation.
Caution: Do not lean on pump when attached to pole!

PATIENT SAFETY

⚠️

Read Instructions for Use prior to use. The infusion device should only be used by specially trained staff.

Intended use

The Infusomat® Space Volumetric Infusion Pump System includes an external transportable electronic volumetric infusion pump, dedicated administration sets, and pump accessories. The system is intended for use on adults, pediatrics, and neonates for the intermittent or continuous delivery of parenteral and enteral fluids through clinically accepted routes of administration. These routes include, but are not limited to intravenous, irrigation/ablation, and enteral. The system is used for the delivery of medications indicated for infusion therapy including but not limited to colloids and cristalloids, blood and blood components, Total Parenteral Nutrition (TPN), lipids, and enteral fluids. The Infusomat® Space Volumetric Infusion Pump System is intended to be used by trained healthcare professionals in healthcare facilities, home care, outpatient, and medical transport environments.

Qualified medical staff should decide how the device should be used based on its features and specifications. For more details, please read the Instructions for Use.

Operation

■ The initial training of the Infusomat® Space P is to be performed by B. Braun sales personnel or other authorized persons. After each software update, the user is required to inform himself about the changes to the device and accessories in the instructions for use.

■ Ensure the unit is properly positioned and secured. The pump must be positioned on a level surface if used in combination with the short stand. Do not position the pump above the patient.

■ Prior to administration, visibly inspect the pump for damage, missing parts or contamination and check audible and visible alarms during selftest.

■ Only connect to patient once the line has been correctly inserted and completely primed. Interrupt connection during line change to prevent incorrect dose delivery.

■ Select infusion line/catheter suitable for use with the intended medical application.

■ Position the infusion line free of kinks.

■ Recommended change of disposable each 24 h (or as per national hygiene regulations).

■ Installation in medically used rooms must comply with the appropriate regulations (e.g. VDE 0100, VDE 0107 or IEC-publications). Observe national specifications and deviations.

■ Do not operate the pump in the presence of flammable anaesthetics to prevent explosion.

- Compare the displayed value with the entered value. Only start the infusion if the values showing are the same.
- If staff call is used we recommend checking the equipment once after connecting the pump.
- Protect the device and the power supply against moisture.
- If the pump falls down or is exposed to force, it must be checked by the service department.
- The displayed data must always be checked by the user prior to making further medical decisions.
- During mobile use (homecare, patient transport inside and outside the hospital): Make sure the device is securely fixed and positioned. Positioning changes and severe shock can lead to minor changes in the delivery accuracy.
- A supplemental patient monitoring must be carried out if life-saving medication is performed.
- The air detector cannot detect air diffusing in the following components: three-way stopcocks, infusion adapters and further lines placed between pump and patient.
- In case high potent drugs are given be sure to have a second infusion pump for that drug at hand.
- Independant of the soft limits the selected values have to be the medically correct ones for the given patient.
- In case values relevant for the dose rate calculation are changing always the flow rate will be updated and the dose rate will be fix.

Enteral Nutrition

The Infusomat Space may be used for entaral nutrition, too. Do not use enteral fluids for intravenous infusion as this may harm your patient. For this reason only use disposables dedicated and labelled for enteral nutrition.

Transfusion

The Infusomat Space may be uses for blood transfusion, too. For this therapy only use disposables dedicated and labelled for transfusion.

Other components

- Use only pressure-proof and compatible disposable items (min. 2 bar/ 1500 mm Hg) to avoid influencing performance data- which would result in impairing patient safety.
- Where several infusion lines are connected on one single vascular access, the possibility of the lines exerting a mutual influence over each other cannot be excluded.

- Refer to respective manufacturer's information for possible incompatibilities of equipment with respect to drugs.

- Use only compatible combinations of equipment, accessories, working parts and disposables with luer lock connectors.

- Connected electrical equipment must comply with the relevant IEC/EN-specifications (e.g. IEC/EN 60950 for data-processing equipment). The user/operator is responsible for the system configuration if additional equipment is connected. The international standard IEC/EN 60601-1-1 has to be taken into account.

Safety Standards

Infusomat® Space P satisfies all safety standards for medical electrical devices in compliance with IEC/EN 60601-1 and IEC/EN 60601-2-24.

- The EMC-limits (electro-magnetic compatibility) according to IEC/EN 60601-1-2 and IEC/EN 60601-2-24 are maintained. If the equipment is operated in the vicinity of other equipment which may cause high levels of interference (e.g. HF surgical equipment, nuclear spin tomography units, mobile telephones etc.) maintain the recommended protective distances from these devices.

- The Infusomat® Space P fulfils the applicable requirements of EN 13718 to be used in the air, on the water and in difficult terrain. During transport the Infusomat® Space needs to be fixed on a suitable restraint system by means of SpaceStation or Pole Clamp SP. When stored under temperature conditions beyond the defined operating conditions the Infusomat® Space P needs to remain under room temperature at least one hour before usage.

- As there is no dedicated norm existing for enteral feeding pumps the safety features of Infusomat Space P are also for enteral nutrition according to the a.m. norms.
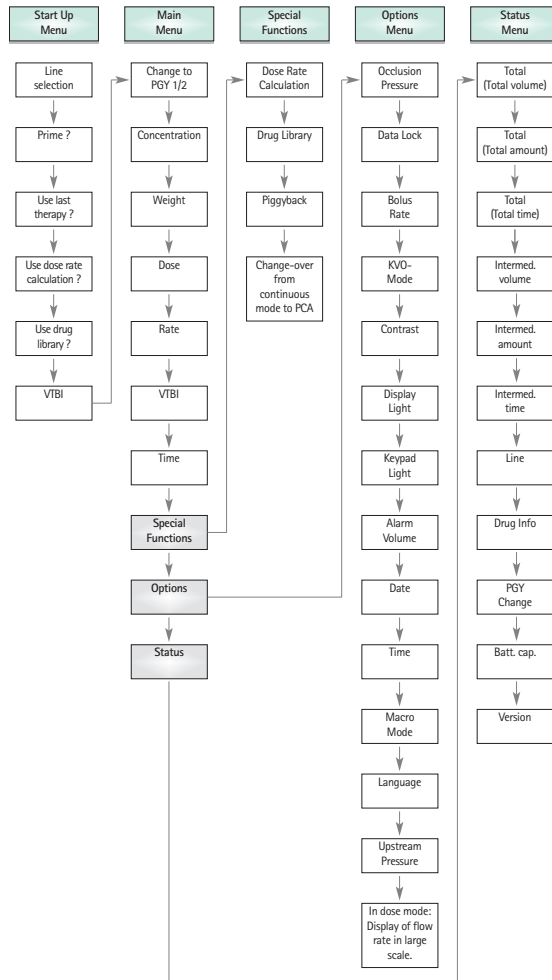
Safety Instructions

- In case the demand button is used with SpaceStation the PCA pump has to be placed in the lowest slot of the lowest SpaceStation.

- Access to the pump settings can be prohibited by DataLock 3. The code for DataLock level 3 should differ from the one for levels 1 and 2 in case the pump is only allowed to be used by pain management professionals.

- When ending PCA and starting it again the therapy data are set to default values.

- Using the demand button also the patient is a permitted user. With the demand button only a PCA-bolus can be requested. This is limited to pre-defined doses by drug list and pump settings.

MENU STRUCTURE / OVERVIEW

Cutline

⏻ On/Off button		Ⓒ Clear button	
⏏ Door open button		OK OK button	
Start/Stop Start/Stop button		⠿ Keypad with arrow up, –down, –left, –right button	
BOL Bolus button		⯬ Connection button	

Menu Structure

| Start Up Menu	Main Menu	Special Functions	Options Menu	Status Menu
Line selection	Change to PGY 1/2	Dose Rate Calculation	Occlusion Pressure	Total (Total volume)
Prime ?	Concentration	Drug Library	Data Lock	Total (Total amount)
Use last therapy ?	Weight	Piggyback	Bolus Rate	Total (Total time)
Use dose rate calculation ?	Dose	Change-over from continuous mode to PCA	KVO-Mode	Intermed. volume
Use drug library ?	Rate		Contrast	Intermed. amount
VTBI	VTBI		Display Light	Intermed. time
	Time		Keypad Light	Line
	Special Functions		Alarm Volume	Drug Info
	Options		Date	PGY Change
	Status		Time	Batt. cap.
			Macro Mode	Version
			Language	
			Upstream Pressure	
			In dose mode: Display of flow rate in large scale.	

The pump can be customized by (de-) activating the menu items of the Start Up (except VTBI) and Options Menu as well as the bolus function via the service program.

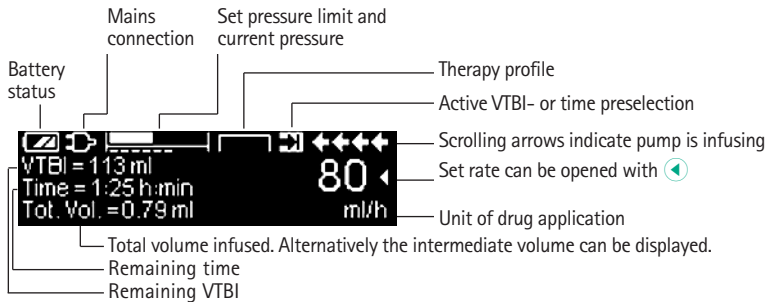# MENU STRUCTURE / NAVIGATION

Display

Meaning

Last Therapy: ☐
Use last Therapy?   Yes ▲
                    No ▼
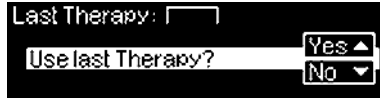
At the top of the screen the last therapy is indicated. Yes/No question can be answered by pressing ▲ for yes or ▼ for no.

OK Confirm   **START** Start Infusion
Rate   __4.__
C Clear   ml/h

Parameters which can be changed (e.g. rate in ml/h) are opened with ◀ or ⓞⓚ. When editing parameters, switch digits/levels using ◀ ▶. White background indicates current digit/level. Use ▲ or ▼ to change current setting. Help text on the bottom/top of the screen indicates options how to proceed (e.g. confirm rate with ⓞⓚ, start infusion with 🔴 or clear rate by pressing 🔵).

Typical display during infusion:

Battery status

Mains connection

Set pressure limit and current pressure

Therapy profile

Active VTBI- or time preselection

Scrolling arrows indicate pump is infusing

VTBI = 113 ml
Time = 1:25 h:min
Tot. Vol. = 0.79 ml   80 ◀
                         ml/h

Set rate can be opened with ◀

Unit of drug application

Total volume infused. Alternatively the intermediate volume can be displayed.
Remaining time
Remaining VTBI

≣ Adren25   0.05
Adrenalin 25mg/50   mcg/kg/h

All status information is available in the bottom line of the dislplay. The desired information can be selected by using ▼ ▲ and will be displayed permanently thereafter (e. g. drug long name, time until syringe empty etc.).

OK Man. Bol. 1200 ml/h   ◀◀◀
Bolus ml   0 ◀
◀ Set Bolus Limit   ml

🟠 has been pressed while the pump is infusing. Start manual bolus at 1200 ml/h by pressing ⓞⓚ (see top of display) or proceed to set bolus limit with ◀ (see bottom of display).

Display
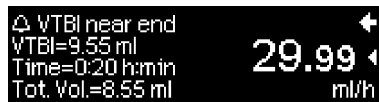
Meaning

This hint pops up if a user tries to edit or change a parameter by pressing ◀ when that parameter is unable to be changed.

Set pressure level with ◀ or ▶ and confirm by pressing OK. Cancel to edit pressure by using C.

Pre-alarms are indicated by a message on the display (e.g. "VTBI near end"), an audible tone and a flashing yellow LED. To confirm a pre-alarm press OK.

In case of an operating alarm (e.g. "VTBI infused") the infusion stops, an audible tone sounds and the red LED flashes. Confirm alarm by using OK. Confirming does not activate an acoustic feedback.

Press and hold ⏻ for 3 sec to turn pump off. A white bar stretches from left to right and counts down the 3 sec. As long there is an infusion line inserted the pump will not turn off but will use standby.

OPERATION

1.1 Start of Infusion

■ Ensure that the pump is properly installed. Check the equipment for completeness and damages. Do not attach the infusion bottle below the pump level.

■ Put the spike vertically into the infusion bottle. Fill the bottom part of the drop chamber by max. 2/3.

■ Fill the infusion line from bottom to top, then close the roller clamp.

■ If the device is connected to the mains, the display indicates the battery status, the mains connection symbol and the last therapy.

■ Press ⏻ to switch on the device. Observe the automatic self-test: The message "Self-test active" and the software version are displayed, two audible tones sound and all three LEDs (yellow, green/red and blue) flash once. Information about the power supply (mains or battery operation) and the set pressure level are indicated. In addition, the line type appears at first (provided that the line is already inserted). Then, the accumulated air volume and the max. size of air bubbles is indicated which is triggering the air alarm of the device.

> The pump offers the possibility to load up to four languages into the pump (depending on the number of the language specific characters), among which the user can choose during the operation of the pump. During the first ever start-up of the device, the user is requested to select the languages and to mark them with ◀. After that, the selection has to be confirmed by choosing the last menu item at the bottom of the list and pressing ⓞⓚ. Then the desired language must be selected with 몸 and confirmed with ⓞⓚ. Answer the following question with ▼ in order to activate the selected language.

■ Press ⓒ to start the direct entry of therapy parameters, or press ⬠ and ▲ to open the pump door in order to continue with inserting the line.

Caution: You may only insert the line while the device is switched on and the line guide element is inserted. Otherwise, there is the danger of freeflow. The pump is permitted to be used on a temperature scale from 18 - 35 °C. Do not use the pump beyond these temperatures. Never leave the pump unattended when inserting the tube.

Caution: Inserting different lines into the pump is identical. Please see instructions and packaging of the different lines (standard, transfusion, opaque, enterel nutrition etc.) to receive information about preparation and usage of these lines.

Insert the infusion line from right to the left. Make sure that the line is routed straight. At first, route the line through the upstream sensor. Then, insert the two-hole clip.

In the next step, attach the white clip without twisting the line.
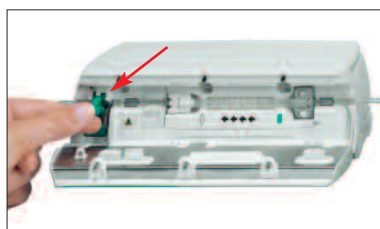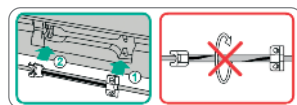
Insert the freeflow clamp (see red arrow) in the opened aperture, in the direction indicated by the arrow, until the opening lever locks in and the safety clamp squeezes the lines (flashing signal lamp goes out).
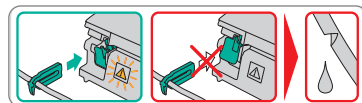
■ Close the pump door. Then select the inserted line with 🭬 and confirm it with ◀. Open the roller clamp.

Caution: If a wrong line is selected the time until the pump goes into a pressure alarm may be prolonged.

■ Press ▲ if the prime function is enabled to prime the infusion line with the rate displayed. Cancel priming with (OK). Repeat the procedure until the line is completely primed. Then press ▼ to proceed.

Note: During priming, all air and drop alarms are switched off.

■ Establish the patient connection.

■ Answer the question whether the old therapy is to be used either with ▲ or ▼ (the question can be deactivated via the service manual). If you select ▲, the pump jumps to the Main Menu. If you select ▼ with no drop sensor connected, you must first enter a VTBI which is smaller than the container filling and confirm it with (OK).

Note: At rates smaller 1 ml/h the detection of a closed roller clamp cannot always be ensured due to physical reasons. Therefore it is recommended especially at small rates to use a drop sensor.

Adjusting the delivery rate:

■ In the Main Menu, open the rate with ◀ and set it with 🔵.

■ Press 🔴 to start the infusion. Running arrows on the display and the green LED indicate that the pump is infusing.

Note: The running infusion can be cancelled at any time by pressing 🔴. The pump can be turned off at any time by pressing ⏻ for 3 sec (Exception: Data lock level 2) and as long a disposable is inserted.

1.2 Entry With Different Combinations of Rate, VTBI (= Volume To Be Infused) and Time

The Infusomat® Space P offers the possibility to enter a volume- and time limit in addition to an infusion rate. When two of these parameters are entered, the third is calculated by the pump. If a volume and/or time is preselected, an arrow symbol is placed in front of one of these parameters in the Main Menu. It is called the "target". During the infusion of the pump, this target symbol is displayed next to the moving arrows in the run display. This indicates that the pump has been programmed, either with a volume- or time limit. The assignment of the target symbol, apparent in the Main Menu, shows the established parameter for the application (VTBI or time). When the rate is changed, the so-called target parameter is principally not adjusted to the new rate but to the parameter which does not have the target symbol in front. After the infusion has started, the remaining VTBI and time are displayed in the Main Menu and the run display (values are counting down).

1.) Enter VTBI and time: The infusion rate will be calculated and displayed on the bottom of the display.
Target: Volume

■ Select VTBI with 🔵 and open with ◀.
■ Enter VTBI with 🔵 and confirm with ⓞⓚ.
■ Select time with 🔵 and open with ◀.
■ Enter time with 🔵 and confirm with ⓞⓚ.

Check calculated rate on plausibility.

Proceed in the same way to calculate 2.) and 3.).

2.) Infusion with volume limit
Enter rate and VTBI: The infusion time will be calculated and displayed on the bottom of the display.
Target: VTBI

3.) Infusion with time limit
Enter rate and time: The infusion volume will be calculated and displayed on the bottom of the display.
Target: Time

Changing already entered values of VTBI and time (rate, VTBI and time already exist at the point of change):

a) Target symbol is placed in front of VTBI:
- Change of VTBI => Adjustment of time. Old and new target: VTBI
- Change of time => Adjustment of rate. Old and new target: VTBI

b) Target symbol is placed in front of time:
- Change of time => Adjustment of VTBI. Old and new target: Time
- Change of VTBI => Adjustment of time. New target: VTBI

1.3 Bolus Application

There are three ways to administer a bolus:

1.) Manual Bolus: Press 🔴. Then press ⓞⓚ and hold button. Fluid is administered for as long as the button is held down. The infused bolus volume is displayed.
The max. bolus time is limited to 10 sec.

2.) Bolus with volume preselection: Press 🔴. Then press ◀ and set bolus dose limit by using ⚙. Press 🔴 to confirm and start bolus. Depending on the service tool settings an acoustic signal will sound after finishing the bolus volume.

3.) Bolus with rate calculation: Press 🔴. Then press ◀ and set bolus dose by using ⚙. Press ⓞⓚ to confirm bolus dose. Set time with ⚙ in which a bolus is to be delivered. Calculated bolus rate is shown on top of the display. Press 🔴 to confirm and start bolus.

The unit of the bolus always depends on the selected dose. If the dose is for example selected as mg/kg/h, then the bolus will be given in mg/kg. If a dose is administered without a relation to the patient's weight (mg/h), then the bolus will be given in mg.

You can use the service program to enter a default and a maximum bolus rate. Once a new therapy is started the device always returns to the default rate – even if the bolus rate was manually changed beforehand..

Note: If the bolus limit is not entered after pressing 🔴, the pump switches back into the run display automatically.

Note: The infused volume during bolus with volume preselection counts up.

In order to purge the line at any time while the pump is stopped press 🔴. Answer the following question by pressing ▲ in order to start the purge process. Cancel by pressing ⓞⓚ or any other key.

Caution: Take care not to overdose! Given a bolus rate of 1200 ml/h, 1 ml will be administered in just 3 sec. To cancel bolus infusion at any time press (ok). At low bolus volumes, under dosages due to the start up characteristic of the pump and the tolerances in the infusion system cannot be excluded. Disconnect patient while purging.

1.4 Infusion Line Change and New Therapy Start

Note: Always interrupt the patient connection before changing a line to avoid dosing errors. Never let the pump run unattended when changing the line. Check and clean the safety clamp regularly.

■ Press 🔴 to stop the delivery. The green LED goes out. Close the roller clamp and interrupt the patient connection.

■ Press 🔵 and open the pump door with 🔼. Press down the green opening lever completely until it locks in place, remove the line and insert a new line.

Note: If for an unknown reason the pump door cannot be opened anymore, you need to take a crank from the inside of the battery compartment cover. Use this crank to remove the emergency aperture cover of the pump. Place the crank in the aperture and turn it clockwise until the pump door opens.

■ Close the pump door, confirm the inserted line with (ok) and open the roller clamp.

■ If required, prime the pump with 🔼. Then press 🔽 to proceed.

■ Establish the patient connection and check the parameters with 🔋.

■ Start the infusion by pressing 🔴.

Note: A new therapy can be started at any time during a stopped infusion. If the pump is in the Main, Status or Options Menu, press 🔵 (repeatedly) and follow the instructions as described.

1.5 End of Infusion

■ Press 🔴 to stop the infusion. The green LED goes out. Close the roller clamp and interrupt the patient connection.

■ Press 🔵. Answer the question whether the pump door is to be opened with 🔼.

■ Press down the green opening lever completely until it locks in place. Remove the line and close the pump door.

■ Press 🔵 for 3 sec to switch off the pump.

Note: The settings will be permanently saved by the switched off device.

1.6 Standby Mode

In the case of extended interruption, the user has the option to maintain the set values.

■ Press 🔴 to stop the infusion. Then press ⏻ for less than 3 sec.

■ Confirm that the device is supposed to switch to stand-by by pressing 🔼.

■ The default time for standby is displayed. Accept the default time with (ok) or change it with 🔹 (0-24 hours) and then confirm it by pressing (ok).

=> While the pump is in the standby mode, it's display shows the drug and the remaining time for this mode. Change of remaining time by pressing (ok). Exit standby by pressing 🔵 .

Chapter 2

ADVANCED OPERATIONS

2.1 Status Request of Pump when Infusion is Running

Press 🔵 to switch between run display and Main Menu while the device is infusing. Navigate through the menu using 🔋 to check parameters. In order to check the menu parameters in the Status-/Options Menu, select "Status" respectively "Options" in the Main Menu, open menu with ◀ and scroll through menu with 🔋.

2.2 Rate, VTBI and Time Change Without Infusion Interruption and Reset Of Status Menu Data

■ Press 🔵 when the pump is in the run display in order to switch to the Main Menu. Select rate/VTBI/time with 🔋 and press ◀ in order to open the parameter.

■ Enter new value with 🎛 and confirm with ⓞⓚ.

Reset Status Menu Data:

The parameters intermediate volume and –time can be reset when the pump is infusing or when the pump has stopped.

■ Select "Status" in Main Menu with 🔋 and press ◀.

■ Highlight intermediate volume (in ml) or intermediate time (in h:min) with 🔋 and open parameter with ◀.

■ Reset values by pressing ▲.

Both parameter total volume and –time, are displayed in the pump as "Total" with the according unit and can be reset by starting a new therapy. A second way to reset the parameters when the pump is in the Main Menu: Press 🔵, answer question whether the last therapy is to be used with u and reset the values with ▲.

The type of the inserted line is displayed in menu item „Line" and cannot be changed once it has been confirmed at the beginning of the infusion. The drug info states the drug name, the name of the drug list and its date of origin. If the change from the secondary to the primary infusion will be performed manually or automatically will be displayed in line "PGY change". The current battery capacity in hours and minutes is displayed in the menu item "Battery Cap." and the current software version in menu item "Version".

SPECIAL FUNCTIONS

3.1 Dose Rate Calculation (Overview)

The dose rate calculation enables a calculation of the rate in ml/h from the entered dose parameters.

$$\text{Infusion rate [ml/h]} = \frac{\text{Dose}}{\text{Concentration}} \times \left[\text{Patient weight (optional)}\right]$$

<u>Setting parameters:</u>
1. Concentration as the amount of the active ingredient per volume.
   - Amount of the active ingredient in µg, mg, mmol, IU or mEq.
   - Volume in ml.
2. Where necessary: Patient weight in kg or lbs.
3. Dose prescription:
   - time related as the amount of the active ingredient per min, h or 24h.
   - time and patient weight related as the amount of the active ingredient per kg per min, h or 24h.
4. Where necessary: VTBI in ml.

3.2 Dose Rate Calculation (Operation)

- Select dose rate calculation with ◀.
- Select the unit of the active ingredient with 🔢 and confirm it with ◀.
- Enter the concentration by entering the amount of the active ingredient and the volume. In order to do so set the values with 🔢 and confirm with (OK).
- If the patient's weight does not need to be entered press ▼.
  Press ▲ for a time and weight related calculation, set the patient weight with 🔢 and confirm it with (OK).
- Select the dose prescription with 🔢 and confirm it with ◀.
- Set the dose with 🔢 and confirm with (OK). The rate will be automatically calculated and displayed at the bottom of the display.
- Check the calculated rate and if necessary the adapted parameters with 🔢 on plausibility before starting the infusion with (Start/Stop).
- Check the parameters with 🔢 on plausibility before starting with (Start/Stop).

Concentration and dose can belatedly be changed in the Main Menu in the same way as the rate, VTBI and time (compare 2.2). The effect of dose modifications on other parameters is shown at the bottom of the display.

Additionally the total and intermediate amount of the infused drug can be

taken from the Status Menu. These can be checked and reset in the same way as the other total and intermediate values.

A deactivation of the dose rate calculation is only possible when the pump is stopped. Press 🟢 from Main Menu and then press 🔽.

3.3 Drug Library

Up to 720 drug names including therapy data and information can be stored in 15 categories. The loading process into the pump can be performed using a separate PC program ("Drug List Editor Space").

Note: The drug library can be started over the Start Up and Special Functions Menu. The user has to make sure prior to the therapy start that the drug library in the pump complies with the patient target group. The name of the drug library (see headline) will be displayed on the pump.

There are different ways of activating the drug library. This can be done while the infusion is running or when the pump is stopped.

On the one hand, a drug name including the according therapy data can be taken from the drug library. On the other hand, if a rate, VTBI and/or time were already defined in the Main Menu, the drug name and the adjusted values of the data set will be loaded.If a dose rate calculation has already been started a belated assignment of the drug name nevertheless is possible.

In the following the loading of a drug including the according parameters will be described:

■ Open the drug library by pressing ◀.

■ Navigate through list with �: and select the drug from category in alphabetical order (all drugs) or within a category with ◀.

■ Confirm the displayed drug information with ◀.

■ Check if the drug short name in the Main Menu is the same as the selected drug. Check the parameter in the Main Menu with �: and start infusion with 🔴.

Hard Limits:

If the set rate/dose/bolus volume and bolus rate exceed the values stored in the drug library (hard limits), the drug will be rejected, a hint will be displayed and the pump will fall back into the drug selection. If this occurs while the pump is infusing the pump will continue to administrate.

Soft Limits:

For the same parameters so called soft limits can be preset via the Drug List Editor. These can be exceeded without any constraint. The following symbols

that describe the status with regard to the soft limits are being displayed:

The infusion is within the range of the minimum and maximum
soft limits   =   ⨲

The infusion is within the range of the maximum soft limit   =   ⊼

The infusion is within the range of the minimum soft limit   =   ⊥

Violation of the upper soft limit   =   ⬆

Violation of the lower soft limit   =   ⬇

No soft limit is defined   =   ⚠

Only a drug name is available   =   ⬥
(It is possible to select a drug name only from the drug library)

The limits of the drug library have to comply with the limits of the pump and the disposable.

Note: An adequate monitoring when infusing highly potent drugs is recommended.

Note: In case a drug from the drug library is selected and the pump is running under dose rate calculation the initial values will be overwritten by the drug library values if selected.

3.4 Patient Controlled Analgesia (PCA)

For PCA a drug list with at least one drug activating the profile PCA is necessary. By this the conditions for an effective and safe therapy are defined.

Switch on pump with ⏻ and wait until self-check is finished. Depending on the settings the choice of a drug is offered direcly or the pump is in "Main Menu".

Select "Special Functions" with ⚇ from "Main Menu" and confirm with ◀.

```
Analgesics
Fentanyl              ◀
Morphine              ▼
↪
```

After the selection the pump offers additional drug related Information which are confirmed by ◀.

```
Fentanyl      ↦PCA    START
Bol.vol       10 mcg        ◀
Limit         100 mcg/1 h   ▼
Lockout       0:05 h:min
```

Select profile PCA by using   and confirm with ⚇ .The therapy settings stored in the drug list are displayed *.

*Bolus volume is the volume of a single bolus the patient may demand. Max. Limit is the amount of drug or volume a patient may demand within a certain time in total. Lockout is the time in between two boli.

Select drug list, category and desired drug by using ⚙.

The therapy can be started now with 🔴 in case all values are defined.

Depending on the pre-defined settings the therapy is started with an initial bolus and a basal rate or not.

Before leaving the patient the pump should be put into DataLock level 3 with ⚙ in Menu "Options". This is necessary especially in case non-authorised access to the settings can be anticipated.

The pump display now may look like this.

The code is entered with ⚙ and confirmed with (ok).

In this state the patient is allowed to demand boli. Depending on the status of the therapy these are either administered or denied. Changing the syringe is also possible by using the code for level 1 or level 2. Altering the settings for PCA or other therapies however is only possible with the code for level 3.

The status of the therapy can be checked in the menu „Status" .

Enter the „Main Menu" with © and select the "Status" with ⚙.

The A/D-ratio indicates the percentage of administered and demanded boli thus giving an idea about the effectivity of the therapy.

An acoustic confirmation of demanded boli can be activated and modulated by 🔲 in Data Lock 3.

Is a demand button connected, the therapy symbol looks like this: **PCA**

In case there is no demand button connected the therapy symbol looks like this: **PCA** .

The demand button is connected to the interface P2 at the rear side of the pump.

Hint: It is possible to start a therapy in continuous mode and switch over to PCA later on (in case the drug is dedicated for use with continuous and PCA application).

3.5   Piggyback Function

The piggyback-mode offers the possibility to interrupt the current (primary) infusion temporarily in order to administer a piggyback (secondary) infusion. Above the pump the piggyback-infusion line is connected with a Y-connector to the administration set. The secondary infusion is supposed to be located approx. 20 cm higher than the primary infusion. All infusion lines need to be completely primed. A back check valve has to be placed according to the drawing (see next page).

A precondition to start the piggyback function is that the pump is stopped.

Note: Please mind to set a VTBI of the primary and secondary infusion that corresponds to the size of the container.

■ Enter the rate manually or load into the pump via the dose rate calculation or the drug library. It is not possible to begin with the secondary infusion if the data for the primary infusion (rate and VTBI) is not set.

■ Select „Piggyback" from the Special Functions Menu and confirm with ◀.

■ The change from the secondary to the primary infusion ("PIGY" to "PRIM") can be done manually or automatically. Correspondingly, if an automatic change is to be made automatically or manually is to be answered with ▲ or ▼.

■ The rate and VTBI of the secondary infusion can be loaded via the dose rate calculation, the drug library or are to be entered manually with ⚬⚬.

■ Start secondary infusion by pressing 🔴. Device delivers the piggyback volume with the set piggyback rate.

Symbols in the headline of the run display ("PRIM" or "PIGY") will indicate if the primary or secondary infusion is currently running.

When the piggyback volume is infused the pump automatically changes to the primary infusion if this was selected. If the VTBI of Primary infusion is infused the pump will continue with the KVO-rate respectively after the KVO-operation the pump stops and activates an alarm. If a manual change from secondary infusion to primary infusion was selected, the pump will stop or continue with KVO after the secondary infusion is completed and the user manually has to change via the menu item "Change to PRIM" in the Main Menu to the primary infusion and start with 🔴.

Note: Switching manually between primary and secondary infusion in the Main Menu is possible at any time while the pump is stopped. It is recommended to keep the roller clamp of the non-active infusion closed.

**Primary
infusion**
e.g. 1000 ml
bag volume
with delivery
rate 25 ml/h

**Secondary
infusion**
e.g. 100 ml
bag volume
with delivery
rate 10 ml/h

1000 ml

100 ml

Clamp

Clamp

Back check valve

Y-connector

Piggyback line

Dripchamber

Roller clamp

Infusion pump

To
patient
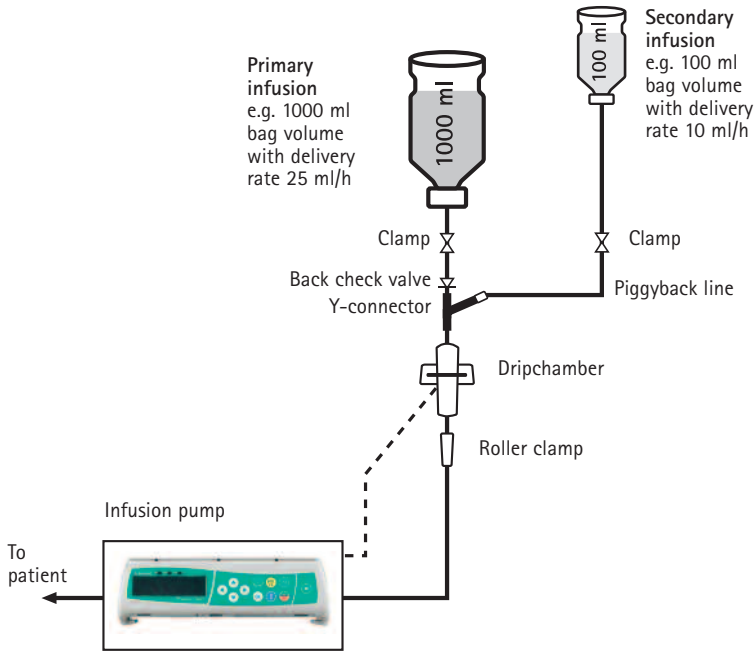
OPTIONS

The options functions may be selected and changed while the pump is infusing or stopped. To edit a menu item, select "Options" in the Main Menu and press ◀. Then select desired function with 🔘 and follow the Instructions for Use as described.

4.1 Occlusion Pressure

The higher the pressure level is set at, the higher the pressure level must rise before triggering an occlusion pressure alarm.

- Enter pressure in Options Menu by pressing ◀.
- Choose between nine pressure levels (1=lowest level; 9=highest level) by pressing ◀ or ▶ and confirm entry with (OK).

4.2 Data Lock

The data lock function protects the device against unauthorized access. A four digit code (default setting "9119"), which can be changed via the service program activates this function in level 1 or level 2. There are three security levels.

Level 1:
A modification of values as well as a bolus application are not possible but a change of the disposable can be conducted. It is possible to navigate through all menus and status data can be checked. Starting, interrupting and switching the pump off is possible.

Level 2:
This level has the same performance characteristic as described under level 1 and additional will not allow the change of disposable. In order to prevent a data lock alarm the correct code must be entered within 20 sec after the pump was stopped. Changing the disposable and switching the pump off is only possible after the code was entered.

Level 3:
This level will allow starting and stopping the pump as well as switching off. The code for this level may be different for each drug and is defined in the drug list. A change of the syringe, however, is possible by using the code defined for the other levels. An overview about the differences between the levels 1, 2 and 3 is given by the following table.

Event	Level 1	Level 2	Level 3
Change of disposable	✓	✗	✓ with code for level 1/2
Start of infusion	✓	✗	✓
Change of parameters	✗	✗	✗
Stop of infusion	✓	✓ 🔔	✓
Switching off pump / Standby	✓	✗	✗ 🔔
PCA bolus with pump–based bolus button	✗	✗	✓
Customisable screen	✗	✗	✓
Acoustic feedback of demanded boli	✗	✗	✓
Indicates denied PCA boli	✓	✓	✗

✓ = possible │ ✗ = not possible │ 🔔 = followed by standby-alarm

Activation of the function:

■ Open data lock in Options Menu with ◀.

■ Select between level 1, 2 or 3 (if activated) with ◀ and ▶ and confirm with (ok).

■ Enter code with 🎲 and press (ok) in order to activate data lock.

Changes to the protected values and the bolus function which are marked with ⊷0 are only possible after entering the code. After 20 sec in the Main Menu, Status Menu, Special Functions Menu and Options Menu the lock will be activated again. If the wrong code is entered twice the pump will switch into the last menu. If the wrong code is entered twice again the pump will go into an audible alarm, a nurse call will go off and the yellow LED blinks. If a target value was reached while data lock is active a new start of the pump is only possible after entering the code.

In order to deactivate the function, select "Off" in the data lock, press (ok), enter the code and press (ok) again.

4.3 Bolus Rate

■ Open bolus rate in Options Menu with ◀.

■ Change bolus rate with 🎲 and confirm setting with (ok).

Note: Set bolus rate according to therapy requirements. Take care not to overdose! Given a bolus rate of 1200 ml/h, e.g. 0.33 ml are reached within just one second.

4.4 KVO–Mode

The pump can continue the infusion with a preset KVO-rate after a preselected VTBI/time has passed (see "Technical Data"). The duration of the KVO delivery is selected in the service program.

- Open the KVO-mode in the Options Menu with ◀.
- Answer the Yes/No question with ▲ to enable the KVO-mode.

4.5 Contrast / Display Light / Keypad Light

Contrast as well as display- and keypad light can be adjusted individually according to the lighting conditions.

- Open contrast/display light/keypad light in Options Menu by pressing ◀.
- Choose between 9 contrast- and display light levels with ◀ or ▶ and confirm with OK.

4.6 Alarm Volume

Chose between 9 different alarm volume levels.

- Open alarm volume in Options Menu with ◀.
- Set volume with ◀ or ▶ and confirm entry with OK.

4.7 Date / Time

- Open date/time in the Options Menu with ◀.
- Modify date and time with ⚬ and confirm the setting with OK.

4.8 Macro Mode

The infusion rate appears larger on the display when the macro mode is activated and the pump is infusing.

- Open macro mode in Options Menu with ◀.
- Answer Yes/No question by pressing ▲ to activate the macro mode.

For quick activation of macro mode: Press and hold ▶ while the pump is infusing until the font size changes.

4.9 Language

This function enables a change of the pump language.

- Open language in the Options Menu with ◀.
- Select language with ⚬ then press ◀.
- Confirm Yes/No question with ▲.

4.10 Upstream Occlusion Pressure

The device is equipped with an upstream pressure sensor that detects an occlusion (e.g. closed roller clamp, kinked line) between the container and the pump. The higher the pressure level is set at, the lower the pressure level must drop before triggering an upstream occlusion pressure alarm.

■   Access upstream pressure in Options Menu by pressing ◀.

■   Choose between nine pressure levels (1=lowest level; 9=highest level) by pressing ◀ or ▶ and confirm entry with ⓞⓚ.

ALARMS

The Infusomat® Space P is equipped with a audible and optical alarm signal.

Alarm-type	Audible signal	Optical signal			Staff call	User confirmation
		Red LED	Yellow LED	Text		
Device Alarm	yes	flashes	flashes	device alarm and alarm code (see service program)	yes	Press 🔘 and follow the instruction on the display.
Opera-ting-Alarm	yes	flashes	off	see alarm description	yes	Press (ок) to acknowledge the audible alarm, alarm text and staff call. The red LED remains on until the infusion is restarted.
Pre-Alarm	yes	off	flashes	see alarm description	(de-)activate via service program	Press (ок) to mute alarm and turn off staff call. Visible alarm remains until end.
Reminder Alarm	yes	off	flashes	see alarm description	yes	Press (ок) to mute alarm, turn off staff call and delete the alarm text.
Alarm Hint	yes	off	off	see alarm description	no	Hint disappears without confirmation.

5.1 Device Alarms

When a device alarm occurs the infusion is immediately stopped. Press 🔘 to switch off the device. Then switch the device on again. In case of a repeated device alarm you must close the rollerclamp, disconnect from the patient, open the front door of the pump and take out the disposable. The device needs to be handed to the service department.

5.2 Pre-Alarms and Operating Alarms

Pre-alarms:
Pre-alarms occur a few minutes (dependable on service settings) prior to operating alarms. During pre-alarms an audible tone sounds, the yellow LED blinks and a staff call is activated (optional). The display message varies depending on the alarm reason. The signal tone and the staff call are turned off with (ок). Display and LED stay in pre-alarm until the operating alarm goes off. Pre-alarms don't lead to an interruption of the infusion.

Display message	Pre–alarm reason
"VTBI near end"	The preselected volume is nearly infused.
"Time near end"	The preselected time is almost over.
"Battery nearly empty"	The battery is almost discharged.
"KVO active"	VTBI/time are reached and the pump continues the infusion at the KVO-rate.
"Communication error"	The pump is located in a system in which at least one device is incompatible or defective. The use of this device in a system is not permitted. The system is to be checked by a service technician.

A stopwatch on the display counts down the remaining time (depending on the service program, between 3-30 min). After that, the pump changes to the operating alarm.

The pre-alarms "VTBI near end" (volume preselection) and "Time near end" (time preselection) can be deactivated via the service program.

Operating alarms:
Operating alarms lead to an interruption of the infusion. An audible tone sounds, the red LED flashes and a staff call is activated. The display states "Alarm" and the reason for the operating alarm. The signal tone and the staff call are turned off with (ok). Corrections are to be made according to the alarm reason.

Display message	Alarm reason
"VTBI infused "	The preselected volume was infused. Continue therapy or select new therapy.
"Time expired"	The preselected time has ended. Continue therapy or select new therapy.
"Battery empty"	The battery pack is discharged. Connect device with mains and/or exchange battery pack. The battery alarm will be on for 3 min. Then the pump will automatically turn off.
"Pressure high"	An occlusion occured in the system. The set pressure level was exceeded. A bolus reduction is automatically initiated by the pump. Check if tubing contains kinks or is damaged as well as IV- and filter patency. Increase occlusion pressure if necessary.
"KVO finished"	The KVO-time has ended. Continue therapy or set new therapy.

"Battery cover removed"	The battery cover is not properly engaged on the battery compartment. When pushing on the battery cover listen for "click".
"Standby time expired"	The set standby time has ended. Set new time or continue with previously set therapy.
"No battery inserted"	It is not possible to use the pump without a battery pack. Turn off pump and insert battery pack according to description "Overview Infusomat® Space P".
"Drive blocked"	Stepper motor does not deliver due to excess pressure in the system. Interrupt patient connection and reinsert the line.
"Calibrate device"	Pump calibration data have changed (e.g. after an update). Recalibrate device via the service program.
"Drop sensor connection"	Contact to the drop sensor is interrupted while the pump is delivering. Check whether the drop sensor is correctly placed on the drop chamber. If necessary, replace the drop sensor or preselect VTBI/time and proceed with therapy.
"Check upstream"	The upstream sensor triggers an alarm. Check if roller clamp is closed or infusion line is kinked. If a drop sensor is connected the upstream alarm is deactivated.
"Air bubble "/"Accumulated air"	Air inside the system. Check the line for small air bubbles and disconnect from patient to repeat priming, if necessary.
"No drops"	The drop sensor does not detect any drops. The infusion container is empty, the roller clamp is closed, the drop sensor is not put on, check the line for obstructions, condensation on drop chamber (remove by shaking it).
"Too few drops"	The number of fallen drops is lower than the preset rate. A negative pressure in a glass infusion container can be eliminated by opening the vent flap on the drop chamber. Check whether the infusion bottle is empty, the roller clamp is completely opened and whether there are any kinks in the line.
"Too many drops"	The number of fallen drops is higher than the preset rate.

	Check the line for damage and make sure that the line is correctly inserted.
"Flow"	Drop chamber is completely filled or leak in the system. Examine the line for damage and check the drop chamber.
"Data were reset"	Therapy and pump settings could not be restored. Enter therapy and pump settings again.
"Therapy data were reset"	Therapy data could not be restored. Enter therapy again.
„Data Lock"	An attempt was made to stop or switch the pump off without entering the code. Enter the correct code in order to continue the therapy respectively turning the pump off.

The red LED doesn't extinguish until the administration is started again respectively the pump is turned off.

Caution: If a wrench is displayed and/or a yellow, red and blue LED blink then the pump is in the service mode and is not permitted to be used on a patient. The pump must then be checked by a service technician.

5.3 Reminder Alarms

Reminder alarms only occur in two cases:

1. A line is inserted, the pump does not deliver, no value is edited and the device is not operated for two minutes.
   An acoustic tone sounds, the yellow LED blinks and a staff call is activated.

   a) The display states "Reminder alarm!"

   b) The display states "Config. not finished!"

   Confirm alarm with (ok) and continue to set therapy/Start Up configuration.

2. A value edition was started but not finished and confirmed. This is also possible with a missing disposable.
   An acoustic tone sounds, the display states "Value not accepted", the yellow LED blinks and a staff call is activated.
   Confirm alarm with (ok) and continue to set therapy.

5.4 Alarm Hints

If inproper entries are made the display states corresponding hints (e.g. "Attention! Rate is out of range"; "The parameter can not be modified") and an audible tone sounds. These hints disappear after a few seconds and don't need to be confirmed.

BATTERY OPERATION AND MAINTENANCE

The Infusomat® Space P is equipped with the latest NiMH-battery. It has an operating lifetime of 4 hours at 100 ml/h when new. For optimal treatment of the battery, the device is equipped with protection against overcharge and deep depletion. The battery pack is charged by the pump during connection to mains. When disconnected from mains or in case of power failure, the pump automatically switches to battery power.

Note: Prior to a longer storage of the pump (> 0,5 months) the battery pack must be completely charged and then removed from the pump. Before changing the battery, always disconnect the pump from the patient and switch off the device.

The battery status indicator is a trend display (low, medium, high). For more detailed information on the current battery capacity (operating time in hours and minutes) please refer to menu item "Batt. Cap." in the Status Menu of the Infusomat® Space P.

Important information for battery self-check:

If the battery symbol is blinking during mains operation, the battery is either discharged or has a reduced capacity. In this case, the pump should not be disconnected from mains. If it is necessary to disconnect the pump from mains power for urgent reasons, the user should check to ensure if the battery capacity is sufficient for the proposed use. When the battery symbol blinks permanently (>1h), the battery must be checked by a technician and replaced if necessary.

Directions for optimal battery use:

The actual battery life may vary due to
- ambient temperature
- varying load (e.g. frequent boluses).

The optimal life time of a battery pack will only be reached if it's ompletely discharged from time to time. A maintenance mode which conducts this battery maintenance is built in. This function should be activated once a month. Furthermore:

- If possible, only charge the battery if it has been completely discharged.
- If a battery, which is not completely discharged, is charged several times, its capacity can be reduced. Its original capacity can be reached again if the battery is completely discharged and then recharged.
- Under normal temperature conditions a battery can be charged and discharged approx. 500 times before its lifetime decreases.
- When the pump is not connected to mains power the battery discharges itself slowly. This can occur even when the pump is not operating. The original capacity will only be reached after several cycles of charging and discharging.
- The battery operating time only can be realized if the pump operates continuously with a fully charged battery at room temperature. The display of the battery operating time on the pump is an approximate value based on the current delivery rate. If the battery is aged it may differ from the actual achievable operating time.

Caution: Batteries may explode or leak if they are opened or incinerated. Consider disposal directions!

Battery maintenance:

To accurately balance the battery capacity a cyclical battery maintenance is necessary. The pump asks the user to perform a battery maintenance every 30 days. The battery maintenance mode detects a possible capacity loss (e.g. through ageing of the battery pack) and then the capacity/running time will be calculated anew. After a longer storage time or a longer operation without battery maintenance it can happen that the battery pre-alarm time can no longer be maintained. In this case it is necessary to perform a battery maintenance.

To initiate the discharge process the message „Battery maintenance" and the (OK)-key will be displayed after switching the pump off. By pressing (OK) and (▲) the discharge process will start. The process is interrupted by switching the pump on again. If the battery maintenance is to be continued a new activation is necessary. After completely discharging the battery it will be completely charged again. The total duration of the battery maintenance process takes approx. twelve hours.

Caution: Please take into account that, if the battery maintenance has not been completed there is a possibility of a reduced battery operating time.

START UP GRAPHS AND TRUMPET CURVES

Start Up Graphs
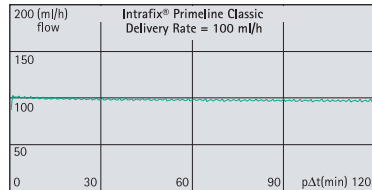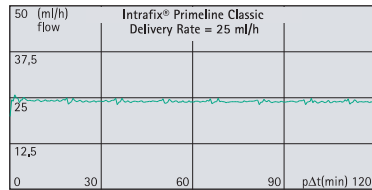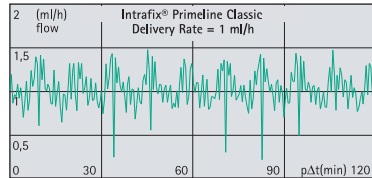
Trumpet Curves
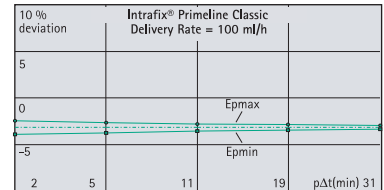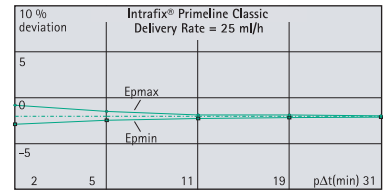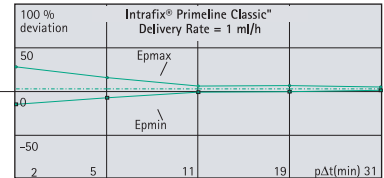
The graphs show the accuracy/uniformity of flow in relation to time. They allow for the following:
The delivery behaviour or delivery precision is essentially influenced by the type of the disposable used. Deviations from the technical data of the pump cannot be excluded if lines (disposables) other than those stated in the order data are used.

Trumpet Curves
Measured values for second hour in each case.
Measurement interval $\Delta t = 0.5$ min
Observation interval $p \times \Delta t$ [min]

Start Up Graphs
Measurement interval $\Delta t = 0.5$ min
Measurement duration $T = 120$ min
Flow Q_i (ml/h)

TECHNICAL DATA

Type of unit	Volumetric infusion pump
Classification (acc. to IEC/EN 60601-1)	{♥} defibrillator-proof; CF equipment □ Protective Class II; Protective Class I in combination with SpaceStation
Class (acc. to Directive 93/42 EEC)	IIb
Moisture protection	IP 22 (drip protected for horizontal usage)
External power supply: ■ Rated voltage	Via B. Braun SpaceStation or optional mains adaptor (rated voltage 100 ... 240 V AC~, 50/60 Hz) for stand alone operation
■ External low voltage	11 ... 16 V DC === via Connection Lead SP 12 V or via SpaceStation
Staff call	Max. 24 V / 0,5 A / 24 VA (VDE 0834)
EMC	IEC/EN 60601-1-2 / 60601-2-24
Time of operation	100 % (continuous operation)

Operating conditions:
  ■ Relative humidity
  ■ Temperature
  ■ Atmospheric pressure
	30 % ... 90 % (without condensation)
	+10 ... +40 °C
	500 ... 1060 mbar

Storage conditions:
  ■ Relative humidity
  ■ Temperature
  ■ Atmospheric pressure
	30 % ... 90 % (without condensation)
	–20 ... +55 °C
	500 ... 1060 mbar

Type of battery pack (rechargeable)	NiMH
Operating time of rechargeable battery	Approx. 4 hours at 100 ml/h
Recharging time	Approx. 6 hours
Weight	Approx. 1.4 kg
Dimensions (W x H x D)	214 x 68 x 124 mm
Volume preselection	0.1 - 99.99 ml in increments of 0.01 ml 100.0 – 999.0 ml in increments 0.1 ml 1000 – 9999 ml in increments 1 ml
Time preselection	00:01 – 99:59 h
Accuracy of set delivery rate	$\pm$ 5 % according to IEC/EN 60601-2-24
Alarm in the case of incorrect dose	For incorrect dosages of 1,4 ml due to malfunctions of the device the pump will automatically shut off
Technical inspection (safety check)	Every 2 years

Rate increments	0.1 - 99.99 ml/h in increments of 0.01 ml/h 100.0 - 999.9 ml/h in increments of 0.1 ml/h 1000.0 - 1200 ml/h in increments of 1 ml/h
Accuracy of bolus infusion	typ. $\pm$ 5 % as of a bolus volume > 1 ml
KVO-rate	Delivery rate $\geq$ 10 ml/h: KVO-rate 3 ml/h Delivery rate < 10 ml/h: KVO-rate 1 ml/h Delivery rate < 1 ml/h: KVO-rate = set rate (default setting 0.1 ml/h)
Computer connection	USB connection in combination with B. Braun interface lead CAN SP (8713230) including electrical insulation. Please pay attention to safety notices.
Air detector	Technical sensitivity: Detection of air bubbles $\geq$ 0.01 ml Alarm triggering: At an air bubble size of typ. 0.02 - 0.3 ml* respectively 1.5 ml/h** (cumulated value over 1 h from air bubbles size 0.01ml).
Sensitivity upstream sensor	9 levels from -0,12 bar to -0,21 bar (pressure reduction)
Occlusion alarm pressures	9 levels from 0.3 - 1.2 bar

Occlusion pressure		Time to occlusion alarm [min] at rate			Max. bolus
	[bar]	[1 ml/h]	[25 ml/h]	[100 ml/h]	[ml]
Level 1	typ. 0.3	05:32	00:28	00:05	0,0059
Level 5	typ. 0.7	21:55	01:03	00:13	0,0625
Level 9	typ. 1.2	37:35	01:38	00:17	0,0723

Mechanical occlusion pressure limit under fault conditions	Occlusion alarm pressure max. 3 bar (300 kPa). Max. bolus volume 2 ml.
History protocol	1000 last history entries. 100 events for system diagnose. Refer to separate documents of the History Viewer for closer information.

* to be set via the service program in increments of 0.01ml

** to be set via the service program from 0.5-3.8 ml/h in increments of 0.1ml

Note: The technical data stated in this Instructions for Use manual were determined with the Infusomat® Space lines as of Intrafix® Primeline Classic (406 2957). These technical data can change when using set configurations.

Chapter 9

WARRANTY / TRAINING / TSC* / SERVICE / CLEANING / DISPOSAL

Responsibility of the Manufacturer

The manufacturer, assembler, installer or importer is responsible for the effects on safety, reliability and performance of the equipment only if:

- assembly operations, extensions, re-adjustments, modifications or repairs are carried out by authorized personnel,
- the electrical installation of the relevant room complies with the appropriate requirements (e.g. VDE 0100, 0107 and/or the IEC-publications resp. national requirements),
- the equipment is used in accordance with the Instructions for Use and
- the Technical Safety Checks are carried out regularly.

The CE mark confirms that this medical product complies with the "Council Directive on Medical Devices 93/42/EEC" dated 14th June 1993.

B. Braun Melsungen AG

Warranty

B. Braun provides 24 months warranty, as from the date of delivery, for every Infusomat® Space P (12 months for every Battery-Pack SP). This covers repair or replacement of parts damaged as a result of design/manufacturing errors or material defects. Modifications or repairs to the unit undertaken by the user/operator or by third parties invalidate the warranty.

The warranty does not cover the following:
Elimination of faults attributable to incorrect/unauthorized handling, or to normal wear and tear.

Training

B. Braun offers a training for version F. Please ask your local representative for further details.

Technical Safety Check*) / Service

The Technical Safety Check is recommended to be carried out every 2 years and should be documented. Servicing work must be carried out exclusively by B. Braun trained personnel.

Check regularly

Check for cleanliness, completeness and damage. Use only according to Instructions for Use. During an exchange interval of the disposable the pump has to perform an occlusion test. Check the following items each time the pump is switched on: self-check, audible alarm, process- and alarm control indication.

Cleaning

Clean external surface of pump using mild soap suds. Do not use spray disinfectants at the mains power connection. Recommended: disinfectant for wiping available from B. Braun (e.g. Meliseptol®). After cleaning, allow the device to vent for at least 1 min prior to use. Do not spray into openings in the device. Be sure to observe the instructions provided concerning waste disposal and hygiene for batteries and disposables. The line guide element can be loosened with the help of a pointed object (e.g. ballpoint pen) which is inserted in the lower right hand corner. The cover can then be cleaned under running water. Spray disinfectant on the peristalsis and wipe it with a soft cloth (Caution: Do not touch peristalsis with sharp object!). When reinserting the line guide element, make sure that it is not damaged and that it audibly locks in. Prime the next infusion line in order to ensure the proper position of each finger. Do not use Hexaquart®.

Disposal

The pumps as well as battery packs can be returned to B. Braun for further disposal. When taking care of disposing of disposables as well as infusion solutions, please consider the applicable hygiene and disposal regulations.

Inspection on Delivery

Despite careful packaging, the risk of damage during transport cannot be entirely prevented. Upon delivery, please check that all items are present. Do not use a damaged device. Contact the service department.
Testing the proper funciton of the device should be performed before initial use. This is even ruled by law in several countries. A respective form can be obtained from B. Braun.

Included in Delivery

Infusomat® Space P, Battery-Pack SP, Instructions for Use-Set.

INSTRUCTIONS FOR USE ACCESSORY

SpaceStation (8713140)

Station for up to four pumps. For further information see Instructions for Use of SpaceStation.

SpaceCover Standard (871 3147)
SpaceCover Comfort (871 3145)

Cover to be placed on upper SpaceStation incl. built-in handle. The SpaceCover Comfort additionaly includes a central alarm management and alarm LEDs.

PoleClamp SP (8713130)

A maximum of three B. Braun Space pumps and one SpaceControl can be stacked together when used with the PoleClamp SP. For detailed instructions on secure fixation of the PoleClamp SP please refer to "Overview Infusomat® Space P" and "Patient Safety".

Power Supply SP (8713110A – 8713114A)

The Power Supply SP is adequate to supply power for a single pump and one SpaceControl.

1.) Connect plug of Power Supply SP with socket P2 on back of pump (ensure that plug "clicks").
2.) Push power plug into wall outlet.

Note: For disconnection from pump, press lever on plug down.
A maximum of three plugs can be stacked upon each other in socket P2.

Technical Data: 100 – 240V AC~, 50/60 Hz

Combi Lead SP 12 V (8713133)

The Combi Lead SP can connect up to three pumps. All pumps can then be operated via the Connection Lead SP (12 V).

1.) Connect plug of the Combi Lead SP 12 V with the socket P2 on the back of the pump.
2.) Connect plug of Connection Lead SP with Combi Lead SP.
3.) Push plug of Connection Lead SP into 12 V connector.

Note: A maximum of three plugs can be stacked upon each other in socket P2.

Drop Sensor SP (8713175)

The drop sensor provides an additional safety function and is therefore particularly recommended in connection with low delivery rates.

The connection of the Drop Sensor SP on the pump is located at the rear of the device, in the lower left corner. At the time of delivery the port of the drop sensor is protected by a cover. Use a screw driver to break off the cover for further disposal.

Use holder on PoleClamp, in order to park the drop sensor.

Short Stand SP (8713135)

Use the Short Stand SP to attach an infusion container to the pump.

Caution: Do only position the pump on a level surface if the pump is used in combination with the short stand.

1.) Push the PoleClamp on the pump.

2.) Plug the short stand into the aperture on the PoleClamp; make sure that it audibly locks in.

3.) To remove the short stand: Press the white button at the lower end of the PoleClamp and remove the short stand.

Battery–Pack SP (8713180)

For further information on the Battery-Pack SP (NiMH) see "Battery Operation".

Interface Lead CAN SP (8713230)

Interface Lead CAN SP is needed in order to set up a connection between the SpaceStation/pump and the computer outlet (for service requirements).

1.) Push plug into socket F3 on the SpaceStation or P2 on the pump and connect with the CAN/USB converter.

2.) Connect CAN/USB converter to computer outlet as described in the Instructions for Use manual.

Caution: The Interface Lead CAN SP is only to be used by the service department; never use while patient is connected.

Note: A maximum of three plugs can be stacked upon each other in socket P2.

Connection Lead SP (12 V) (8713231)

Install the Connection Lead SP (12 V) in the following way:

1.) Connect plug to socket P2 on back of pump or F3 on SpaceStation respectively.

2.) Put the connection lead into the car socket.

3.) If necessary, remove red adaptor of motor vehicle connector by slightly turning and simultanously pulling.

The green LED of the electronic box shows the operating voltage. The mains connector can easily be replaced by another plug if required.

Caution: Do not connect the pump to a patient during external car battery charging!

Note: A maximum of three plugs can be stacked upon each other in socket P2.

Connection Lead for Staff Call SP (8713232)

To connect the Infusomat® Space P to staff call, use the Connection Lead for Staff Call SP. The staff call needs to comply with the requirements of VDE 0834 (consider country specific regulations).

Note: Test staff call signalling before every use.

The Infusomat® Space P offers three different staff call operating modes. They are displayed in the signalling scheme. Consider the staff call of the hospital when choosing an operating mode. Choose the operating mode via the service program.

		turned off	turned on	turned off
static without Off–Alarm*)	Alarm Operation		Operating Alarm	
dynamic without Off–Alarm	Alarm Operation		1 sec	
dynamic with Off–Alarm	Alarm Operation		1 sec	1 sec
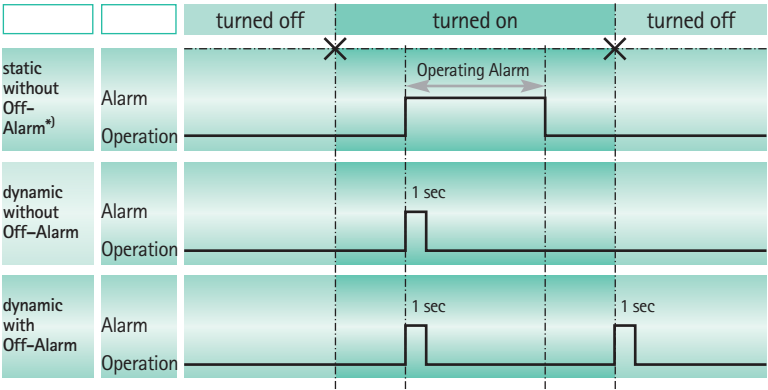
*) in the mode static without Off-Alarm, the staff call can be surpressed with (ok)

Caution: The user should always closely observe the local pump alarms as well.

Note: A maximum of three plugs can be stacked upon each other in socket P2.

Technical Data

	Connecting Wire	
	white and green	white and brown
Alarm	disconnected	connected
Operation	connected	disconnected

Polarity of connexion is arbitrary:
max. 24 V / 0.5 A / 12 VA

PCA-ACCESSORIES

■ Space PCA-Kit (REF 8713554) consisting of: :

- Demand button
- Hook and loop tape
  for fixation of the demand button at
  the patient´s arm
- Line fixation
  connection between hook and loop tape
  and demand button
- Metal clip
  alternatively for fixation at the bed
  sheet
- Cable strap
  for wrapping the cable of the demand
  button
- PCA-Key
  for locking the syringe holder or the Syringe Anti Removal Cap

Fixation of the demand button:

at the wrist: or at the bed sheet:

Usage of the cable strap:

Art. No.

B. Braun Infusomat® Space P (100 – 240 V) 871 3070

Recommended accessories for the B. Braun Infusomat® Space P:

SpaceStation.............. ....871 3140
SpaceCover Standard...871 3147
SpaceCover Comfort..871 3145
PoleClamp SP 871 3130
Power Supply SP (Euro Plug)..871 3110A
Power Supply SP (UK Plug) 871 3111A
Power Supply SP (US Plug) 871 3112A
Power Supply SP (Australian Plug)..871 3113A
Power Supply SP (Universal Plug)...871 3114A
Power Supply SP (RSA Plug)...871 3115A
Combi Lead SP 12 V...871 3133
Drop Sensor SP 871 3175
Short Stand SP...871 3135
Battery-Pack SP (NiMH) 871 3180
Interface Lead CAN SP...871 3230
Connection Lead SP (12 V) 871 3231
Connection Lead for Staff Call SP 871 3232

Infusomat® Space P Lines:

Intrafix Primeline Classic; 150 cm..406 2957
Intrafix Primeline Comfort; 180 cm..406 2981L
Intrafix Primeline Comfort, BCV; 150 cm..406 3252
Intrafix Primeline Comfort, BCV; 180 cm..406 3287
Intrafix Air P; 180 cm 406 2981
Intrafix Air P; 230 cm..406 0407
Intrafix Air P, with siliconised spike; 180 cm..406 2990
Intrafix Air P, with Y-Injection Piece; 230 cm 406 0202
Intrafix Air-matic P; 150 cm..406 3953
Intrafix Air-matic P; 180 cm..406 3988
Intrafix Air-matic P; BCV; 150 cm...406 3759
Intrafix Air-matic P, BCV; 180 cm...406 3783
Intrafix SafeSet; 180 cm..406 3000
Intrafix SafeSet, BCV; 180 cm...406 3001
Intrafix SafeSet P, 230 cm...406 3003
Intrafix SafeSet P, I.S., 180 cm..406 3005

Other Lines:
Fresenius Perfudrop Air M-P 48403608
Codan L86 P 43.4304
Codan V86 P...43.4291

Hint: B. Braun does not have any influence on the quality of other lines.
Changes in quality of those lines may have an influence on the technical
characteristics of the pump.. B. Braun therefore is not liable for deviations
caused by disposables from other vendors than B. Braun. In case of inadequate
performance caused by these disposables please contact the correspondant
manufacturer.

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